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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,128	03/15/2004	Bradley J. Glenn	04005.101	3404
41689	7590	06/05/2007		
BRADLEY P. HEISLER HEISLER & ASSOCIATES 3017 DOUGLAS BOULEVARD, SUITE 300 ROSEVILLE, CA 95661			EXAMINER BLANCO, JAVIER G	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 06/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/802,128

Applicant(s)

GLENN ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 46-53 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 8, 9, 13, 16, 18-22, 46-49, and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 7, 10-12, 14, 15, 17, 50, 51 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 1, 12, 14, 15, and 17 in the reply filed on March 26, 2007 is acknowledged.
2. Applicants' cancellation of claims 23-45 in the reply filed on March 26, 2007 is acknowledged.
3. Applicants' addition of claims 46-53 in the reply filed on March 26, 2007 is acknowledged.

Election/Restrictions

4. Newly submitted claims 46-49 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the product as claimed can be used in a materially different process of using that product. For example, said product can be used in a surgical procedure to treat a clogged vessel (i.e., stent). Also, the process for using the product as claimed can be practiced with another materially different product. For example, the materially different product could be a flowable polymer that will cure in place once implanted.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 46-49 (non-elected invention/group) AND claim 52 (non-elected species) are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3, 7, 10-12, 14, 15, 17, 50, 51, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 1, newly added limitation: “said center line being non-circular when said helical spring is unloaded and at body temperature” is vague, rendering claim 1 indefinite as to the scope of the invention. Nowhere in claim 1 there is an indication the implant is loaded into (or to) an instrument/tool. Claims 2, 3, 7, 10-12, 14, 15, and 17 depend on claim 1.

b. Regarding claim 12, newly added limitation added to claim 12 is vague, rendering claim 12 indefinite as to the scope of the invention. What is “adapted to be oriented vertically” (see line 2), the helical spring, or the “direction perpendicular to said center line”? Also, the claim seems contradictory. According to the language therein, the width is defined as “being in a direction perpendicular to said center line” (see lines 3-5). But lines 1-2 requires “said helical spring is shorter, in a direction perpendicular to said center line and adapted to be oriented vertically when implanted, than it is wide”. It seems claim 12 claims the width as shorter than the width.

c. Regarding claim 17, newly added limitation added to claim 17 is vague, rendering claim 17 indefinite as to the scope of the invention. What is “adapted to be oriented vertically” (see line 2), the helical spring, or the “direction perpendicular to said center line”? Also, the claim seems contradictory. According to the language therein, the width is defined as “being in a direction perpendicular to said center line” (see lines 3-5). But lines 1-2 requires “said helical spring is

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shorter, in a direction perpendicular to said center line and adapted to be oriented vertically when implanted, than it is wide". It seems claim 17 claims the width as shorter than the width.

d. Regarding claim 50, the limitation: "said center line being non-circular when said helical spring is unloaded and at body temperature" is vague, rendering claim 50 indefinite as to the scope of the invention. Nowhere in claim 50 there is an indication the implant is loaded into (or to) an instrument/tool. Claims 51-53 depend on claim 50.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 7, 10-12, 14, 15, 17, 50, 51, and 53 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lam (US 5,556,413).

Referring to Figures 1 and 2, Lam discloses an implant (1) comprising a helical spring (body 5) having a plurality of turns (helically-shaped elements 32) about a center-line; said center-line located with a plane (the location of the plane is arbitrary); said helical spring *adapted to flex* in a direction transverse to compression loads; and said center line being non-circular (e.g., linear). Said helical spring exhibits a substantially barrel-shaped outline (see Figure 2) with ends (10, 20) of said helical spring shorter in height than a middle portion of said helical spring (see Figure 2; see column 6, lines 50-54). Because of the shape of vascular vessel, the center line may extend at least slightly arcuately (i.e., an arcuate portion of the vessel) or

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substantially linear (i.e., a linear portion of the vessel) when the helical spring is unloaded. Said helical spring is formed of nickel titanium alloy having a martensite phase and an austenite phase (see column 12, lines 10-15). As it is well known in the art, the helical spring is adapted to be placed within a delivery cannula (see column 2, lines 34-40) or an outer catheter sheath (see Figure 9).

Note: The intended use recitations carry no patentable weight in the absence of any distinguishing structure. Also, claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

9. Claims 1-3, 7, 10-12, 14, 15, 17, 50, 51, and 53 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Steffen (DE 101 30 825 A1).

Referring to Figure 1, Steffen discloses an implant comprising a helical spring (shape memory spiral 3) having a plurality of turns about a *substantially* linear center-line. A turn height of said spring is *substantially* similar to a height of a space between two vertebrae. A “height” could arbitrarily be any height within the space between two vertebrae. Also, it should be noted that “a height of a space between two vertebrae” varies according to patient’s age and/or

condition. Said helical spring is *substantially* barrel-shaped (i.e., *substantially* ellipsoidal) with ends of said helical spring shorter in height than a middle portion of said helical spring.

Note: The intended use recitations carry no patentable weight in the absence of any distinguishing structure. Also, claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

10. With regards to the 102(b) rejection based on Steffen (DE 101 30 825 A1), Applicants’ arguments filed March 26, 2007 have been fully considered but they are not persuasive.

a. The Applicants argue that Steffen does not disclose “said center line extending within a plane located between the two vertebrae”. The Examiner respectfully disagrees. The location of said “plane located between the two vertebrae” is not exactly defined, and is therefore arbitrary. The space between two vertebrae may comprise several planes. Also, it is noted the “center line” is not defined (e.g., “from a proximal end of the implant to a distal end of the implant”) in the claim language, and is therefore arbitrary as well. In Figure 1 of Steffen (DE 101 30 825 A1), the center line may arbitrarily be the line across the largest turn of the implant, and hence the implant

is “adapted to encounter compression loads transverse to said center line” and “adapted to flex in a direction transverse to said center line responsive to said transverse loads”.

11. Claims 1-3, 14, 50, 51, and 53 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lin (US 5,716,416 A).

Referring to Figures 1B and 1C, Lin discloses an implant (implant 100) comprising a helical spring (see inner spring shown in Figures 1B and 1C) having a plurality of turns about a center-line, which center-line is substantially linear when said helical spring is located within the cannula/endoscope/tool 300/500. A turn height of said spring is *substantially* similar to a height of a space between two vertebrae (see Figures). A “height” could arbitrarily be any height within the space between two vertebrae. Also, it should be noted that “a height of a space between two vertebrae” varies according to patient’s age and/or condition. Said helical spring is made of a shape-retaining titanium-base material, or an alloy material made of cobalt, molybdenum, and nickel (see column 2, lines 51-57).

Note: The intended use recitations carry no patentable weight in the absence of any distinguishing structure. Also, claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

12. With regards to the 102(b) rejection based on Lin (US 5,716,416 A), Applicants' arguments filed March 26, 2007 have been fully considered but they are not persuasive.

a. The Applicants argue that Lin does not disclose "said center line extending within a plane located between the two vertebrae". The Examiner respectfully disagrees. The location of said "plane located between the two vertebrae" is not exactly defined, and is therefore arbitrary. The space between two vertebrae may comprise several planes. Also, it is noted the "center line" is not defined (e.g., "from a proximal end of the implant to a distal end of the implant") in the claim language, and is therefore arbitrary as well. In Figures 1B and 1C of Lin '416, the center line may arbitrarily be a line across the body (at any point) of the implant, and hence the implant has a non-circular center line, and the implant is "adapted to encounter compression loads transverse to said center line" and "adapted to flex in a direction transverse to said center line responsive to said transverse loads".

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

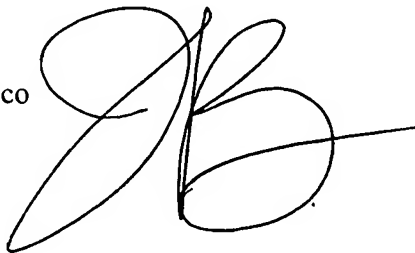

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco
May 16, 2007

A large, stylized handwritten signature in black ink, consisting of a large 'J' and 'B' intertwined.A handwritten signature in black ink, appearing to read 'D. Willse'.

David H. Willse
Primary Examiner